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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/449,096	11/24/1999	BERNARD ACKERMAN	ACKRAD-5	5859

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 01/12/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/449,096

Applicant(s)

ACKERMAN, BERNARD

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9 and 11-23 is/are pending in the application.
- 4a) Of the above claim(s) 17-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9 and 11-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3763

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Wright (US Pat# 5,707,358).

Wright discloses a dual concentric balloon catheter (10) that includes a tubular body with a lumen having an external opening (23,24 or 40) adjacent the first end and a balloon (11). The lumen also includes a second opening (27 or 28) in fluid communication with the interior of the balloon. The external opening adjacent the first end generates a back-flow within the lumen which causes the fluid to enter and inflate the balloon through the second opening (see 4:14-18). The external opening has a predetermined area and the second opening has a predetermined area, the predetermined area of the second opening is greater than the predetermined area of the external opening (see 4:19 and 4:23-25). The catheter body is made from a silicone elastomer and therefor flexible. The device also includes a moveable sheath (22) that can be moved to a first position (sutured position) to cover a portion of the body to add rigidity and can be moved to a second position (suture-free) to uncover a portion of the body (see 3:44-46). The balloon can be inflated to form substantially elliptical and spherical shapes (see figures 2 and 6). The balloon is made from polyurethane (see 4:35). Regarding the function language, the prior art device is

Art Unit: 3763

considered capable of achieving the function as claimed since this reference meets all the structural limitations of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 11-16 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright.

Wright meets the claim limitations as described above but fails to include a syringe for delivering fluid to the catheter. At the time of the invention, it would have been obvious to incorporate a syringe into the invention. Syringes are well known in the art to be used as a balloon inflation mechanism. One skilled in the art would have relied on their knowledge of commonly used devices for inflating balloon in order to use an easily accessible mechanism to perform the procedure of the device.

Response to Arguments

Applicant's arguments filed 10/23/03 have been fully considered but they are not persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., single lumen

Art Unit: 3763

and single balloon) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Regarding applicant's assertion that Wright does not disclose an external opening adjacent to the first end that generates a back flow within the lumen which causes the fluid to enter and inflate the balloon through the second opening, attention is drawn to column 4 lines 14-28. This passage clearly sets forth that the openings (23,24, and 40) at the end of the catheter are structured to create a pressure differential during infusion to inflate the self-inflating balloon through four balloon apertures (27 and 28).

Applicant did not argue combining a syringe with the prior art device of Wright. Instead applicant relied on the previous argument that Wright itself does not teach each and every element of the claimed invention. Therefore, the examiner assumes that applicant does not contest the catheter – syringe combination.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3763

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-2192.

Catherine Serke Williams *CSW*.
January 10, 2004

Brian L. Casler
BRIAN L. CASLER
SUPERVISORY ENGINEER
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